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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,652	07/07/2000	Richard J. Zeman	001290.091198	8034

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/611,652	Applicant(s) ZEMAN ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,21-31 and 37-43* is/are pending in the application.

4a) Of the above claim(s) *2,3,5,8,10,21-31,38,39 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 6, 7, 9, 37, 40, 42, and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The cancellation of claims 11-20 and 32-36 in amendment filed March 25, 2002 is acknowledged. The addition of claims 37-43 in amendment filed March 25, 2002 is acknowledged.

Claims 1-10, 21-31, and 37-43 are pending.

The elected species is clenbuterol, as stated in response filed September 10, 2001, Paper No. 5.

Claims 2, 3, 5, 8, 10, 38, 39, and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Claims 21-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions.

The outstanding rejection of claim 9 under 35 USC 112, first paragraph is withdrawn in view of the amendment filed March 25, 2002.

The outstanding rejection of claims 1 and 4 under 35 USC 102(a) over Zeman et al. is withdrawn in view of the amendment filed March 25, 2002. The claims now recite the method steps of administering from about 0.5 to about 100 μg/kg of clenbuterol to the patient.

The outstanding rejection of claims 1, 4, 6, and 7 under 35 USC 102(a) over Etlinger et al. is withdrawn in view of the amendment filed March 25, 2002. The claims now recite the method steps of administering from about 0.5 to about 100 μg/kg of clenbuterol to the patient with spinal cord contusion or neuronal degeneration.

The outstanding rejection of claims 1 and 4 under 35 USC 102(a) over Sayers et al. is withdrawn in view of the amendment filed March 25, 2002. The claims now recite the method steps of administering from about 0.5 to about 100 μg/kg of clenbuterol to the patient.

The examiner notes that it is improper for claims 6-7, and 9 depending from succeeding claims 37, 40, and 41.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 7, 9, 37, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sayers et al. (Society for Neuroscience Abstracts 1998; 24: abstract 125.2).

Sayers et al. teaches the use of 1mg/kg/day of clenbuterol in treating spinal cord injury (See the last paragraph of the abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sayers et al.

Sayers et al. teaches the use of 1mg/kg/day and 10mg/kg/day of clenbuterol in treating spinal cord injury in rats (See the last paragraph of the abstract). Sayers et al also teaches that spinal cord injured animals receiving the high dose clenbuterol treatment (10mg/kg/day) have almost complete recovery (See abstract, second to last paragraph).

Sayers et al. does not expressly teach the dosage of clenbuterol as 0.5 to about 100 μg/kg or about 40μg/kg.

It would have been obvious to one skill in the art when the invention was made to employ 0.5 to about 100 μg/kg or about 40μg/kg in the method of rehabilitation for spinal cord injury.

One of ordinary skill in the art would have motivated to employ 0.5 to about 100 μg/kg or about 40μg/kg in the method of rehabilitation for spinal cord injury because the effect of clenbuterol in the instant method of treatment is known and the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Claims 1, 4, 6, 7, 9, 37, 40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Etlinger et al. (WO99/09966), reference of record in the previous office action mailed October 24, 2001.

Etlinger et al. teaches administration of clenbuterol in a dosage of about 0.5 to 1000.0 μg/day/kg to treat scoliosis (See page 5, line 27; page 9, line 18-19; also page 11, example 1). Etlinger et al. also teaches the spinal cord injury is at the lower thoracic spine (T10-11) (See particularly page 11, line 28-31). Etlinger et al. also teaches scoliosis may be caused by the neuromuscle weakness which is resulted from a spinal cord injury (See page 1, second paragraph).

Etlinger et al. does not expressly teach the dosage of clenbuterol as 0.5 to about 100 μg/kg or about 40μg/kg.

It would have been obvious to one skill in the art when the invention was made to employ 0.5 to about 100 μg/kg or about 40μg/kg in the method of rehabilitation for spinal cord injury.

One of ordinary skill in the art would have motivated to employ 0.5 to about 100 μg/kg or about 40μg/kg in the method of rehabilitation for spinal cord injury because the effect of clenbuterol in the instant method of treatment is known and the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan, absent evidence to the contrary.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and

unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the experiment data of page 9-19 in the instant specification has been considered but are not found persuasive. The dosage of clenbuterol used in the experiment was 1.6mg/kg body wt/ day, which is 1600μg/kg body wt. This dosage of clenbuterol was shown to be effective in treating spinal cord injury; however, it is outside the clenbuterol dosage range recited in the claims herein.

Response to Arguments

Applicant failed to provide a response to the outstanding rejection under 35 USC 103 over Sayer et al. set forth in the previous office action mailed October 24, 2001. Therefore this outstanding rejection under 35 USC 103 over Sayer et al. remains.

Applicant's arguments with respect to claims 1, 4, 6, 7, 9, 37, 40, 42, and 43 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200